

APPLICANT(S): YEDGAR, Saul et al.  
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## **REMARKS**

Claims 1-21 are pending in the application. Claims 1-21 have been rejected. Claims 3-6 and 9-21 have been canceled without prejudice or disclaimer. Applicants reserve all rights in these claims to file divisional and/or continuation patent applications. Claims 1 and 8 have been amended, and new claims 22-30 have been added. Support for amended claims 1 and 8 and for new claims 22-32 can be found throughout the specification as filed and on page 8 paragraph 129, page 14 paragraph 250, page 9 paragraph 141, and in the table on page 11.

Applicants respectfully assert that no new matter has been added.

## **CLAIM REJECTIONS**

### **35 U.S.C. § 112 Rejections**

In the Office Action, the Examiner rejected claims 8-14 under 35 U.S.C. § 112, as being indefinite. Claim 8 is directed to a method of treating a subject suffering from an intestinal disease comprising administering a pharmaceutical composition comprising a lipid or phospholipid moiety bonded to a polysaccharide. Accordingly, Applicants request withdrawal of the rejection.

### **35 U.S.C. § 101 Rejections**

In the Office Action, the Examiner rejected claims 8-14 under 35 U.S.C. § 101 as allegedly reciting a use without setting forth steps involved in the process. Claims 9-14 have been cancelled, rendering the rejection of these claims moot. Applicants submit that claim 8 is directed to a method of treating a subject suffering from an intestinal disease comprising administering a pharmaceutical composition comprising a lipid or phospholipid moiety bonded to a polysaccharide. Accordingly, Applicants request withdrawal of the rejection.

### **35 U.S.C. § 102 Rejections**

In the Office Action, the Examiner rejected claims 15-21 under 35 U.S.C. § 102(b), as allegedly being anticipated by Aoki et al, US 5,470,578. Applicants disagree. Applicants maintain that the compounds disclosed by Aoki are different than the compounds for use in the subject application and do not anticipate them, nor render them obvious. Aoki describes a

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single phospholipid conjugated to a spacer that is conjugated to a glycosaminoglycan, while the compounds for use in the subject Application are multiple phospholipids directly conjugated to a glycosaminoglycan at multiple sites of the glycosaminoglycan. Compounds with different structures have different properties and thereby different functional effects.

In addition, Aoki does not describe using his compounds to treat an intestinal disease. Thus, Aoki uses different compounds for a different purpose than that claimed in the subject application. Aoki therefore does not anticipate nor render obvious the claims of the subject Application. However, in order to expedite prosecution of the subject Application, Applicants have cancelled claims 15-21, rendering the rejection moot.

### **35 U.S.C. § 103 Rejections**

In the Office Action, the Examiner rejected claims 1-21 under 35 U.S.C. § 103(a), as allegedly being unpatentable over the combined teachings of Yedgar et al., US 5,064,817, Chaikof et al., US 6,171,614 and Aoki et al., US 5,470,578, in view of Pruzanski et al., US 6,043,231, Sorgente et al., US 6,162,787, and Falk et al., US 6,022,866.

The claimed invention is directed to a method of treating a subject suffering from an intestinal disease, comprising the step of administering to a subject a lipid or phospholipid moiety bonded at multiple sites to a glycosaminoglycan (GAG) via an amide or ester linkage.

The Examiner alleged that Yedgar et al. disclose the use of distearoyl phosphatidylethanolamines covalently bonded through their amino groups to polysaccharides to treat hyper-secretory disease states.

The compounds that Yedgar discloses are not the claimed compounds of the present invention. Yedgar's compounds comprise a lipid or phospholipid conjugated to an inert carrier, while the compounds of the present invention comprise a lipid or phospholipid conjugated to a GAG, which is biologically active. Moreover, Yedgar does not describe a phospholipid moiety bonded via an amide or ester linkage to a glycosaminoglycan.

In addition, Yedgar also does not disclose the claimed use of the compounds of the present invention - treating intestinal disease. It is not obvious that all hyper-secretory diseases, each with unique causes, symptoms, and preferred methods of treatment, would be treatable with the compounds of Yedgar. Moreover, Yedgar does not describe the use of the compound claimed in the instant invention to treat intestinal diseases, as was demonstrated specifically in

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Example 2. Thus, neither the compounds nor the uses of Yedgar are applicable to the instant invention. Accordingly, Applicants request withdrawal of the rejection.

Although the Examiner alleged that Chaikof et al. disclose therapeutic glycophospholipids, including chondroitin sulfate, Chaikof's compounds are not equivalent to the compounds for use in the subject Application, because they comprise an ether bond rather than an amide or ester bond. Moreover, Chaikof does not describe treating intestinal disease. Thus, Chaikof neither describes the compounds of the present invention nor the use of any compound in treating intestinal disease.

The Examiner alleged that Aoki et al. discloses compositions that overlap with Applicants' compositions to treat rheumatoid arthritis. The compounds of Aoki are not comparable because they comprise phospholipids terminally conjugated to a GAG via a carrier molecule, typically a single saccharide unit, while in the subject Application, the phospholipid is directly conjugated to the GAG, at multiple sites on the molecule. Further, Aoki does not describe treating intestinal disease. Thus, neither the compounds nor the uses of Aoki are applicable to the instant invention.

The Examiner alleged that Falk et al. describes using hyaluronic acid to treat restenosis and that Sorgente et al. describes the use of chondroitin sulfate as an anti-inflammatory compound. Both references describe the use of an unconjugated GAG, and neither describes the use of any compound for treating intestinal disease. Notably, **unconjugated GAGs are not as effective as conjugated polysaccharides** (Figs. 1.2, 1.3, 7.3, 8.7, 8.8, 12.1, and 15.1 and Table 5.3), so neither Falk nor Sorgente are appropriate references in this context. Thus, neither the compounds nor the uses of Falk nor Sorgente are applicable to the instant invention.

Pruzanski et al. describe the use of a single modified tetracycline in treating inflammatory bowel disease. Pruzanski's compound, however, is structurally dissimilar not only to the claimed compounds, but to the compounds of Yedgar, Chaikof, Aoki, Falk, and Sorgente as well. Therefore, there would be no motivation to combine the references. Thus, Pruzanski is not an appropriate reference in this context.

In summary, none of the references describe the use of the claimed compound nor their use in treating an intestinal disease. Accordingly, Applicants request withdrawal of the rejection.

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**Double Patenting Rejections**

In the Office Action, the Examiner provisionally rejected claims 15-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims in copending U.S. Application Number 09/756,765. Claims 15-21 have been cancelled, rendering the rejection moot. Applicants request withdrawal of the rejection.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

  
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